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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF: Randal K. BUDDINGTON et al. ART UNIT: 1618
SERIAL NO.: 09/671,106 EXAMINER: Simon J. OH
CONFIRMATION NO.: 8636
FILING DATE: September 28, 2000
FOR: INHIBITION OF SYSTEMIC INFECTIONS IN HUMANS AND
 VERTEBRATES BY DIETARY FIBERS

APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37

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SIR:

In support of Appellants' appeal of the Examiner's final rejections, dated February 26,
2006, submitted herewith is Appellants' Brief on Appeal.

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<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
6,241,983	June 5, 2001	Paul et al.
6,500,805	December 31, 2002	Van Loo et al.

I. Real Parties in Interest

The real parties in interest in this patent application are:

Mississippi State University
306 Bowen Hall, Hardy Road
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II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of Claims

Claims 18-20, 23-24, 27, 30-31, 33-34, 37 and 41-50 are pending in this application. Claims 18-20, 23-24, 27, 30-31, 33-34, 37 and 41-50 are rejected. The rejected claims, all of which are the subject of this appeal, are set forth in Appendix A.

IV. Status of Amendments

In the Amendment filed on May 15, 2006, subsequent to the final rejection on appeal, Appellants sought amendments to independent Claims 20, 27 and 37. The Examiner indicated in the Advisory Action mailed July 25, 2006, that those amendments were not entered because they raised a new issue. Thus, the claims set forth in Appendix A are the claims recited in an Amendment which was filed on November 22, 2005.

V. Summary of Claimed Subject Matter

Claims 18-20, 23, 24, 41, 42 and 47 are directed to a method for the treatment of infections in humans or vertebrates comprising: administering to humans or vertebrates having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*, a composition consisting essentially of: an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Support for Claims 18-20, 23, 24, 41, 42 and 47 can be found on page 6, lines 2-6; page 9, lines 9-19; page 10, line 23; page 11, lines 1-3; page 13, lines 10-20; page 14, lines 1-15; page 15, lines 1-7; page 16, lines 14-21; page 17, lines 1-10; and Figures 1 and 2.

Claims 27, 30, 31, 33, 34, 43, 44 and 48 are directed to a method for the treatment of an infection occupying the lymph or blood in humans or vertebrates comprising: administering to humans or vertebrates having an infection caused by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella* in the lymph or blood, a composition consisting essentially of: an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Support for Claims 27, 30, 31, 33, 34, 43, 44 and 48 can be found on page 6, lines 2-6; page 9, lines 9-19; page 10, line 23; page 11, lines 1-3; page 13, lines 10-20; page 14, lines 1-15; page 15, lines 1-7; page 16, lines 14-21; page 17, lines 1-10; and Figures 1 and 2.

Claims 37, 45, 46, 49 and 50 are directed to a method for the treatment of infections in humans or vertebrates, comprising: administering to humans of vertebrates having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*, a functional food composition consisting of traditional nutrients and an effective amount of inulin and/or oligofructose to treat said infection; wherein the food composition is administered orally or through tube feeding.

Support for Claims 37, 45, 46, 49 and 50 can be found on page 6, lines 2-6, page 9, lines 9-19; page 10, line 23; page 11, lines 1-3; page 13, lines 10-20; page 14, lines 1-15; page 15, lines 1-7; page 16, lines 14-21; page 17, lines 1-10; and Figures 1 and 2.

VI. Grounds of Rejection to be Reviewed on Appeal

The Examiner repeatedly rejected Claims 18-20, 23-24, 27, 30-31, 33-34, 41-46 and 47-50 under 35 U.S.C. 103(a) as being obvious over Paul et al., USPN 6,241,983 (hereinafter “Paul”), and Van Loo et al., USPN 6,500,805 (hereinafter “Van Loo”).

VII. Arguments

In spite of the voluminous and multifaceted arguments of nonobviousness presented by Appellants in their responses dated May 27, 2004; October 19, 2004; February 17, 2005; May 27, 2005; August 4, 2005; November 22, 2005 and May 15, 2006, the Examiner continues to reject claims 18-20, 23-24, 27, 30-31, 33-34, 41-46 and 47-50 under 35 U.S.C. §103(a) as being obvious over Paul and Van Loo. Appellants believe that these rejections are clearly contrary to established

U.S. law concerning obviousness, for they ignore a number of claim limitations which unambiguously distinguish over the prior art. These points are discussed below.

I. Paul and Van Loo, individually or in combination, fail to teach or suggest every limitation of the claimed invention.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Independent Claim 20 of the present application is directed to a method for the treatment of infections in humans or vertebrates comprising: administering to humans or vertebrates having **an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella***, a composition **consisting essentially of** an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Independent Claim 27 is directed to a method for the treatment of an infection occupying the lymph or blood in humans or vertebrates comprising: administering to humans or vertebrates having **an infection caused by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida*, *Listeria* and *Salmonella* in the lymph or blood**, a composition **consisting essentially of** an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Independent Claim 37 is directed to a method for the treatment of infections in humans or vertebrates, comprising administering to humans or vertebrates having **an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella***, a functional food composition **consisting essentially of** an effective amount of inulin and/or oligofructose to treat said infection; wherein the food composition is administered orally or through tube feeding.

In contrast, Paul generally describes a composition that lowers the intestinal pH and inhibits the overgrowth of gastrointestinal pathogens. The composition contains an effective amount of a beneficial human intestinal microorganism and an effective amount of dietary fiber. Paul does not teach or suggest treating existing infections caused by an invasion of the lymph or the blood stream by pathogenic bacteria.

The Examiner asserts that Paul discloses that (1) the compositions disclosed therein promote the growth of beneficial bacteria, which lowers the intestinal pH, which then inhibits the overgrowth of gastrointestinal pathogens; and (2) hyper-proliferation of harmful bacteria in the gastrointestinal tract is associated with increased **susceptibility** to systemic infections (col. 10, lines 13-22 and 37-45). The Examiner further asserts that Paul discloses the treatment of a local gastrointestinal infection with the same composition (col. 16, lines 21-28). The Examiner then broadly interprets these disclosures as reading on the treatment of existing infections caused by an invasion of the lymph or the blood stream by pathogenic bacteria. The Examiner's interpretation is clearly improper for the reasons set forth below.

First, Paul simply mentions that hyper-proliferation of harmful bacteria in the gastrointestinal tract is associated with increased **susceptibility** to systemic infections. Paul does not teach or suggest that existing infections caused by an invasion of the lymph or the blood stream by pathogenic bacteria can be treated by inhibiting hyper-proliferation of harmful bacteria in the gastrointestinal tract. Nor does Paul provide any evidence that Paul's composition may be effective in treating such infections. Furthermore, Paul never mentioned any link between proliferation of harmful bacteria in the gastro-intestinal tract and infections caused by invasion of the blood stream or lymph by pathogenic bacteria.

The Examiner also alleges that "the Paul et al. patent further states that the disclosed compositions can be used for treating conditions facilitated by infections caused by pathogenic microorganisms such as E.coli, Salmonella, and Candida (See Column 16, Lines 21-26)." (Office Action of February 27, 2006, page 3, lines 3-5).

Appellants respectfully submit that the cited passage in Paul refers to "treating diarrhea, constipation, and other types of gastrointestinal distress due to infection with pathogenic microorganisms such as E. coli, Salmonella, Candida, rotavirus, and Cryptosporidium." (Paul, col. 16, lines 21-26)." One skilled in the art would understand that the "infection" referred to in this passage is a local infection in the gastrointestinal tract and is not an infection "caused by an invasion of the lymph or the blood stream by pathogenic bacteria." An infection "caused by an invasion of the lymph or the blood stream by pathogenic bacteria" would lead to symptoms such as fever and swollen lymph nodes, but not diarrhea or constipation. Accordingly, Paul does not disclose treating an existing infection of blood stream or lymph, much less using a composition consisting essentially of inulin or oligofructose to treat such infections.

Moreover, Paul does not mention anything about the use of inulin and/or oligofructose as the only active ingredient for treating established infections in humans and vertebrates caused by an invasion of the lymph or the blood stream by pathogenic bacteria. In fact, one of the key ingredients in Paul's composition is beneficial bacteria or immunoglobulin. Paul specifically teaches that

“a dietary supplement containing dietary fiber without living intestinal bacteria that are beneficial for gastrointestinal health lack means for providing an inhibitory effect on the growth of pathogenic bacteria, reducing levels of toxic amines, and lowering the pH of the gastrointestinal tract.... Further, prior art formulas that fail to include concentrated immunoglobulins lack means for binding and inactivating foreign antigens such as pathogenic bacteria, viruses, fungi, and protozoa that can infect the gastrointestinal tract and are detrimental to the health thereof.” (col. 2, line 64 to col. 3, line 16).

The instant invention is directed to a composition **consisting essentially of** an effective amount of inulin and/or oligofructose. Therefore, Paul actually teaches away from using the instant invention because the present composition **does not contain** beneficial bacteria in combination and **does not** contain immunoglobulin.

Therefore, based on the teaching in Paul, one skilled in the art would not use the composition claimed in the instant application to inhibit the growth of pathogenic bacteria in the gastrointestinal tract, let alone infections caused by an invasion of the lymph or the blood stream by pathogenic bacteria.

Van Loo does not cure the deficiency of Paul. Van Loo generally describes a method for treating colon cancer with a composition comprising dietary fiber. Van Loo, however, is absolutely silent with respect to the possible use of inulin and/or oligofructose for the treatment of established infections in humans and vertebrates caused by an invasion by pathogenic bacteria of the lymph or

the blood stream. Therefore, Van Loo fails to teach or suggest treating "an infection caused by an invasion of the blood stream by *Listeria* or *Salmonella*."

Accordingly, Paul and Van Loo, individually or in combination, do not render claims 20, 27 and 37 obvious because they fail to teach or suggest every limitation of those claims.

It has been well established that if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed Cir. 1988).

Accordingly, Claims 18, 19, 23, 24, 41, 42 and 47 are patentable because they depend from Claim 20. Claims 30, 31, 33, 34, 43, 44 and 48 are patentable because they depend from Claim 27.

Claims 45, 49 and 50 are patentable because they depend from Claim 37.

II. There is no motivation to combine the references as suggested by the Examiner.

When applying 35 U.S.C. §103, the Examiner is required to adhere to the following tenets of patent law: (1) the claimed invention must be considered as a whole; (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination . . . *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Furthermore, "teachings of references can be combined only if there is some suggestion or incentive to do so." *In re Sang Su Lee*, (USPQ F.2d 1430) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed. Cir. 1984)). Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *Id.* Moreover, the Court states "even when the level of skill in the art is high, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious". *Id.*

As described above, independent Claim 20 is directed to a method for the treatment of infections in humans or vertebrates comprising: administering to humans or vertebrates having **an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella***, a composition **consisting essentially of** an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Independent Claim 27 is directed to a method for the treatment of an infection occupying the lymph or blood in humans or vertebrates comprising: administering to humans or vertebrates having **an infection caused by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida*, *Listeria* and *Salmonella* in the lymph or blood**, a composition **consisting essentially of** an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Independent Claim 37 is directed to a method for the treatment of infections in humans or vertebrates, comprising administering to humans or vertebrates having **an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella***, a functional food composition **consisting essentially of** an effective amount of inulin and/or oligofructose to treat said infection; wherein the food composition is administered orally or through tube feeding.

In contrast, Paul describes a method for inhibiting hyper-proliferation of harmful bacteria in the gastrointestinal tract using a composition containing dietary fiber, beneficial bacteria, and optionally, immunoglobulin. As described above, Paul actually teaches away from inhibiting harmful bacteria with a composition consisting essentially of inulin and/or oligofructose.

Van Loo generally describes a method for **treating colon cancer** with a composition comprising dietary fiber. Van Loo is absolutely silent with respect to the possible use of inulin and/or oligofructose for the treatment of established infections in humans and vertebrates caused by an invasion by pathogenic bacteria of the lymph or the blood stream.

Accordingly, a skilled artisan, with no knowledge of the claimed invention would have no motivation to combine Paul with Van Loo in the manner claimed in the present application. In other words, the teachings of Paul and Van Loo do not make it obvious to one skilled in the art that a composition consisting essentially of an effective amount of inulin and/or oligofructose can be used to treat an infection caused by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida*, *Listeria* and *Salmonella* in the lymph or blood. Besides, even a combination of the teachings of Paul and Van Loo would not teach the claimed subject matter of claims 20, 27 and 37. Therefore, Claims 20, 27 and 37 are patentable over Paul and Van Loo.

As discussed above, Claims 18, 19, 23, 24, 41, 42 and 47 are patentable because they depend from Claim 20. Claims 30, 31, 33, 34, 43, 44 and 48 are patentable because they depend from Claim 27. Claims 45, 49 and 50 are patentable because they depend from Claim 37.

III. The cited references do not provide a reasonable expectation of success.

When applying 35 U.S.C. §103, in addition to the legal requirements discussed above in section II, the Examiner is also required to adhere to the following tenets of patent law: . . . (3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (4) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As discussed above, Paul describes a method for inhibiting hyper-proliferation of harmful bacteria in the gastrointestinal tract using a composition containing dietary fiber, beneficial bacteria, and optionally, immunoglobulin. Paul specifically notes that a dietary supplement containing dietary fiber without beneficial bacteria and/or immunoglobulins lacks means for inhibiting the growth of pathogenic bacteria.

Van Loo simply describes a method for treating colon cancer with a composition comprising dietary fiber. Van Loo does not mention anything about treating established infections caused by an invasion by pathogenic bacteria of the lymph or the blood stream using inulin and/or oligofructose. As pointed out by the CAFC in *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988), “[T]he admonition that “obvious to try” is not the standard under § 103 has been directed mainly at two kinds of error . . . In others, what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” *Id.* Accordingly, even if one of ordinary skill in the art were to combine Paul and Van Loo, there would be no reasonable expectation of success, as required by MPEP §2143.02. The

Examiner has suggested the combination of Paul and Van Loo with the benefit of impermissible hindsight afforded by the claimed invention.

Accordingly, one skilled in the art would not be able to produce the invention of Claims 20, 27 and 37 based on Paul and Van Loo without undue experimentation. Consequently, the unexpected effect of treating a pathogenic infection of the lymph or blood using a composition consisting essentially of inulin and/or oligofructose shown in Examples 1 and 2 of the instant application render the claimed invention not obvious to one skilled in the art to derive the present invention from the prior art of record.

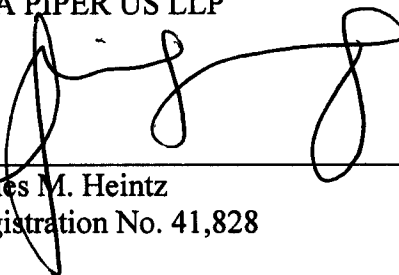
Accordingly, Claims 20, 27 and 37 are patentable over Paul and Van Loo. Claims 18, 19, 23, 24, 41, 42 and 47 are also patentable because they depend from Claim 20. Claims 30, 31, 33, 34, 43, 44 and 48 are patentable because they depend from Claim 27. Claims 45, 49 and 50 are patentable because they depend from Claim 37.

VIII. CONCLUSION

For the reasons discussed above, the references of Paul and Van Loo taken alone or in combination do not support a *prima facie* case of obviousness with respect to claims 18-20, 23-24, 27, 30-31, 33-34, 41-46 and 47-50 of the present application. Appellants submit that these rejections are clearly contrary to established U.S. law concerning obviousness and reversal of the 35 U.S.C. §103 rejection is respectfully requested.

Respectfully submitted,

DLA PIPER US LLP

A handwritten signature in black ink, appearing to read 'James M. Heintz', is written over a horizontal line. The signature is stylized with loops and a long horizontal stroke.

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APPENDIX A

1-17. (Canceled).

18. The method according to Claim 20, wherein the inulin is chicory inulin with an average degree of polymerization \overline{DP} of at least 20.

19. The method according to Claim 18, wherein the inulin is chicory inulin with an average degree of polymerization \overline{DP} of at least 25.

20. A method for the treatment of infections in humans or vertebrates comprising:
administering to humans or vertebrates having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*, a composition consisting essentially of:
an effective amount of inulin and/or oligofructose to treat said infection; and
one or more pharmaceutically acceptable excipients,
wherein the composition is administered orally or through tube feeding.

21-22. (Canceled).

23. The method of Claim 20, wherein the human or vertebrate is an adult human and the amount of inulin administered to the adult human ranges from 5 to 40 g/day.

24. The method of Claim 20, wherein the human or vertebrate is an adult human and the amount of inulin administered to the adult human ranges from 5 to 25 g/day.

25-26. (Canceled).

27. A method for the treatment of an infection occupying the lymph or blood in humans or vertebrates comprising:

administering to humans or vertebrates having an infection caused by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella* in the lymph or blood, a composition consisting essentially of:

an effective amount of inulin and/or oligofructose to treat said infection; and

one or more pharmaceutically acceptable excipients,

wherein the composition is administered orally or through tube feeding.

28-29. (Canceled).

30. The method according to Claim 27, wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 20.

31. The method according to Claim 27, wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 25.

32. (Canceled).

33. The method of Claim 27, wherein the human or vertebrate is an adult human and the amount of inulin administered to the adult human ranges from 5 to 40 g/day.

34. The method of Claim 27, wherein the human or vertebrate is an adult human and the amount of inulin administered to the adult human ranges from 5 to 25 g/day.

35-36. (Canceled).

37. A method for the treatment of infections in humans or vertebrates, comprising:
administering to humans or vertebrates having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*, a functional food composition consisting of traditional nutrients and an effective amount of inulin and/or oligofructose to treat said infection;

wherein the food composition is administered orally or through tube feeding.

38-40. (Canceled).

41. The method of Claim 20, wherein the human or vertebrate is a vertebrate and wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 20.

42. The method according to Claim 41, wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 25.

43. The method of Claim 27, wherein the human or vertebrate is a vertebrate and wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 20.

44. The method according to Claim 43, wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 25.

45. The method of Claim 37, wherein the human or vertebrate is a vertebrate and wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 20.

46. The method according to Claim 37, wherein the inulin is chicory inulin with an average degree of polymerization $\overline{(DP)}$ of at least 25.

47. The method of Claim 20, wherein said composition consists essentially of an effective amount of oligofructose.

48. The method of Claim 27, wherein said composition consists essentially of an effective amount of oligofructose.

49. The method of Claim 37, wherein said food composition consists of traditional nutrients and an effective amount of oligofructose.

50. The method of Claim 37, wherein the human or vertebrate is an adult human and the amount of inulin administered to the adult human ranges from 5 to 40 g/day.